



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

PD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/984,099	12/03/97	MCBRIDE	K CGNE-115-1-U
------------	----------	---------	----------------

HM22/0127

CARL J. SCHWEDLER  
CALGENE, INC.  
1920 FIFTH STREET  
DAVIS CA 95616

EXAMINER

CAMPELL, B

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

01/27/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

87984,099

Applicant(s)

McBride et al

Examiner

Campell

Group Art Unit

1632

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/28/99, 12/20/99.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-10, 12-16, 18-28, 30-39, 42-64 is/are pending in the application.  
Of the above claim(s) 62, 63 is/are withdrawn from consideration.
- ☒ Claim(s) 23-26, 61 is/are allowed.
- ☒ Claim(s) 1-10, 12-16, 18-22, 27, 28, 30-39, 42-60, 64 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 6
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1632

The amendments and terminal disclaimer filed September 28, 1999 and December 20, 1999 have been entered.

***Election/Restriction***

Newly submitted claims 62 and 63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 62 and 63 claim nucleotide sequences which are unrelated to those previously claimed. A new search would be required for these independent and distinct inventions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 62 and 63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Furthermore, claims 1-10, 12-16, 18-22, 27, 28, 30-39, 42-59 and 64 will only be considered to the extent that they encompass sequences previously examined.

***Specification***

The amendment filed September 28, 1999 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The brief description of the drawings for Figures 7-13 includes terms which are not supported in the specification as filed, including "the Ltp promoter region from a cotton fiber specific lipid transfer protein gene," "pCGN5198," "pCGN5616," "pCGN5148," "pCGN5149." Furthermore, there is no disclosure in the specification as filed of the production of plants transformed with the cited constructs, so there is no support for "measurements" performed on these plants.

Art Unit: 1632

Applicants are required to cancel the new matter in the reply to this Office action. Alternatively, Applicants may wish to import into the specification portions of the disclosure of PCT/US96/09897, to which the instant application claims priority.

The computer readable form of the sequence listing submitted September 7, 1999 is in compliance with the requirements of 37 CFR 1.821 through 1.825. However, the paper copy of the sequence listing was not accompanied by an amendment directing that it be entered into the specification, and so it has not been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Written Description***

Claims 1-10, 12, 13, 28, 30-39 and 42-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are referred to the interim guidelines on written description published December 21, 1999 in the Federal Register at Volume 64, Number 244, pp. 71427-71440.

The claims are drawn to DNA constructs comprising a promoter sequence active in cotton fiber cells. However, the specification only discloses the 4-4-6 and rac13 promoter sequences isolated from cotton. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In this case, the sequences provided in SEQ ID Nos. 7, 11 and 15 are the only species whose complete structure is disclosed (the promoter sequences within SEQ ID Nos. 7 and 11 are apparently identical). Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence). In this case, no additional

Art Unit: 1632

information is provided, other than the biological activity Applicants hope will be possessed by promoters isolated by the recited method. In particular, the Rac9 promoter recited in claim 60 has not been disclosed. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of promoters besides those shown in SEQ ID Nos. 7, 11 and 15 at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Applicants argue that the recitation of how the promoter sequences are to be isolated constitutes a description of the sequences themselves. This argument is not persuasive. Other than the disclosed embodiments noted above, Applicants have not provided a complete structure for any other promoter which could be isolated by screening a genomic library with cDNAs. No other identifying characteristics have been disclosed, nor is there any correlation between structure and the recited function.

#### *Enablement*

Claims 1-10, 12-16, 18-21, 27, 28, 30-39, 42-60 and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID Nos. 7, 11, 15 and any other promoters which may be obtained by hybridization with these promoters, does not reasonably provide enablement for all the claimed promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass promoters obtained from genomic clones of any plant species which hybridize under fairly low stringency conditions with coding sequences expressed in cotton fibers. One can not predict what will hybridize with the 4-4 and rac 13 cDNAs, particularly since no function is disclosed for the encoded proteins. Once a hybridizing genomic sequence is obtained, one must determine where the transcription start site is located (i.e. define the 3' end of the promoter). There is no simple method for determining the 5' end of the promoter, since promoter elements which control tissue specificity can be located hundreds of bases upstream of the transcription start site and Applicants have not identified any

Art Unit: 1632

structural features of the disclosed promoters which cause expression in cotton fiber tissue. Thus the only way to determine whether a promoter construct is active in cotton fiber tissue is to produce transgenic plants containing the promoter construct. This is a large quantity of experimentation, even though (as Applicants argue) the skilled artisan knows how to perform the individual steps required. Furthermore, while Applicants argue that the claims only require that the promoter be "functional" in a cotton fiber cell, the only disclosed purpose for isolating and using such a promoter is to modify the phenotype of cotton fibers. One can not predict whether a promoter isolated by the recited method would be suitable for the claimed methods. A promoter which is "functional" at low levels, or only during a brief developmental stage, for example, would not be useful for the purposes contemplated in the specification. Finally, with regard to claim 44, the specification does not disclose any gene encoding an enzyme which degrades indigo or melanin.

For the reasons discussed above, it would require undue experimentation to make and use the full scope of the claimed invention. This is particularly true given the nature of the invention, the breadth of the claims, the amount of experimentation necessary and the unpredictable nature of the art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-16, 18-21, 27, 28, 30-39, 42-60 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 1, 44, 57, 59 and 64 are indefinite and incorrect because some of the recited sequences are not cDNA.

Claim 64 is an improper dependent claim because it encompasses sequences not included in claim 1.

### ***Conclusion***

Art Unit: 1632

Claims 23-26 and 61 are allowed. Other allowable subject matter is disclosed. Allowable claim language is suggested below:

1. A DNA sequence comprising as operably joined components in the direction of transcription, a cotton fiber transcriptional factor functional in a cotton fiber cell and an open reading frame encoding a protein in a pigment biosynthesis pathway wherein said transcriptional factor is selected from the group consisting of
  - a) nucleotides 65-4163 of SEQ ID No: 7,
  - b) SEQ ID No: 15,
  - c) a DNA sequence which hybridizes with SEQ ID No: 15 under conditions comprising hybridization in a solution comprising 50% formamide, 5X SSC, 0.1% SDS, 5 mM EDTA, 10X Denhardt's solution, and 25 mM sodium phosphate at pH 6.5 with 250 µg/ml carrier DNA, and washing in 2X SSC, 0.1% SDS at 42°C for 3 X 30 minutes.

Similar language could be used in claims 44, 57, 59 and 64. These claims would be allowable at the present time as discussed in the interview of October 19, 1999.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be

Art Unit: 1632

reached on Monday-Thursday from 8:00 to 4:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink that reads "Bruce Campell". The signature is written in a cursive style with a large, stylized "B" and "C".

**BRUCE R. CAMPELL  
PRIMARY EXAMINER  
TECHNOLOGY CENTER 1600**